UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------------------------|----------------------|------------------------------|------------------|
| 10/581,171 | 05/31/2006 | Nafizal Hossain | 06275-513US1 101293-1P US | 1661 |
| ²⁶¹⁶⁴ FISH & RICH <i>A</i> | 7590 03/24/200 ARDSON P.C. | EXAMINER | | |
| P.O BOX 1022 | | CHANG, CELIA C | | |
| MINNEAPOLIS, MN 55440-1022 | | | ART UNIT | PAPER NUMBER |
| | | | 1625 | |
| | | | | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 03/24/2009 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

| | Application No. | Applicant(s) | | |
|---|--|--|--|--|
| | 10/581,171 | HOSSAIN ET AL. | | |
| Office Action Summary | Examiner | Art Unit | | |
| | Celia Chang | 1625 | | |
| The MAILING DATE of this communication ap Period for Reply | pears on the cover sheet with the c | correspondence address | | |
| A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING D - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period - Failure to reply within the set or extended period for reply will, by statut Any reply received by the Office later than three months after the mailin earned patent term adjustment. See 37 CFR 1.704(b). | DATE OF THIS COMMUNICATION 136(a). In no event, however, may a reply be tir will apply and will expire SIX (6) MONTHS from e, cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). | | |
| Status | | | | |
| 1) Responsive to communication(s) filed on <u>09 A</u> 2a) This action is FINAL . 2b) This 3) Since this application is in condition for allowated closed in accordance with the practice under A | s action is non-final. ance except for formal matters, pro | | | |
| Disposition of Claims | | | | |
| 4) Claim(s) <u>1-19</u> is/are pending in the application 4a) Of the above claim(s) is/are withdra 5) Claim(s) is/are allowed. 6) Claim(s) is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) <u>1-19</u> are subject to restriction and/or | awn from consideration. | | | |
| Application Papers | | | | |
| 9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) acceptable and applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the E | cepted or b) objected to by the drawing(s) be held in abeyance. Section is required if the drawing(s) is ob | e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d). | | |
| Priority under 35 U.S.C. § 119 | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>5/31/06, 3/9/07</u> . | 4) Interview Summary Paper No(s)/Mail D: 5) Notice of Informal F 6) Other: | ate | | |

Application/Control Number: 10/581,171

Art Unit: 1625

DETAILED ACTION

Page 2

1. This application is a 371 of PCT/SE2004/001771.

Claims 1-19 as filed on May 31, 2006 are pending.

2. Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim 8, drawn to q=1, spiro-benzofuran-piperidinyl compounds. Classified in class 546 subclass various depending on species election. If this group is elected, a further election of a single disclosed species is also required. Generic claims 1-7, 9-11 reading on q=1 can be prosecuted together with the election.

Group II, claims 1-7, 9-11 remaining compounds, drawn to q=0, spiro-benzofuran-pyrrolidinyl compounds classified in class 548, subclass various depending on species election. If this group is elected, a further election of a single disclosed species is also required.

Group III, claims 13-19, drawn to method of modulating chemokine receptors classified in class 514 subclass various depending on species election. If this group is elected, a further election of a single disclosed disorder and a single disclosed species effective in treating the elected disorder is also required.

The inventions are independent or distinct, each from the other because:

Compounds of groups I and II differ in elements, bonding arrangements and utility to such an extend that one reference anitcipating one group would not render the other group obvious. The searches for each group is not coextensive since separate core must be searched indendently. Lacking of common is one of the reason for restriction.

Inventions I-II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP

Application/Control Number: 10/581,171

Art Unit: 1625

§ 806.05(h). In the instant case the method of treating rheumatoid arthritis can be practice with products that inhibits COX2 function such as celebrax.

Page 3

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above <u>and</u> there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the

Art Unit: 1625

inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is *presented prior to* final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be **allowable**, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai; In re Brouwer and 35 U.S.C.§ 103(b)," 1184 O.G. 86 (March 26, 1996).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include all the limitations of the product claims. *Applicants are reminded of propriety of process of use claims in consideration*

Application/Control Number: 10/581,171 Page 5

Art Unit: 1625

of the "reach-trough" format, which is drawn to mechanistic, receptor binding or enzymatic functionality. Reach through claims are considered lacking of descriptive and enabling support from the specification. Thus, rejoinable process of use claims are those with particular disease named with efficacy support from the specification for treating the particular disease. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01. Filing of appropriate terminal disclaimer in anticipation of a rejoinder may speed prosecution and the process of rejoinder.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang Mar. 17, 2009 /Celia Chang/ Primary Examiner Art Unit 1625